



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/523,225	01/31/2005	Sean Mark Dalziel	CL2148USPCT	8041

7590 03/20/2008
E I Du Pont De Nemours and Company
Legal Patents
Wilmington, DE 19805

EXAMINER

DEES, NIKKI H

ART UNIT	PAPER NUMBER
----------	--------------

1794

MAIL DATE	DELIVERY MODE
-----------	---------------

03/20/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/523,225	Applicant(s) DALZIEL ET AL.	
	Examiner Nikki H. Dees	Art Unit 1794	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 January 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 and 10-17 is/are rejected.
- 7) ☒ Claim(s) 8-9 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 31 January 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>23 May 2005</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Objections

1. Claims 8-9 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from any other multiple dependent claim. See MPEP § 608.01(n). Accordingly, the claims have not been further treated on the merits.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 5, 16 and 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Claim 5 uses a trademark as a limitation to identify a particular product. The claim scope is uncertain since the trademark cannot be used properly to identify any particular product. See MPEP 2173.05(u).

5. Claim 16 provides for the use of a coated carrier particle or coated matrix particle to produce a product, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass.

A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

6. Claim 17 provides for the use of a coated carrier particle or coated matrix particle to administer a pharmaceutical to a mammal, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim Rejections - 35 USC § 101

7. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 16 and 17 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1, 2 and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Schurr (WO 97/07879).

10. Schurr (p. 3 lines 18-31) teaches the following:

Further in accordance with the present invention, there is provided a process for coating a solid particle with a coating material. The process comprises the steps of metering a liquid composition comprising the coating material into a flow restrictor having an outlet end; injecting a gas stream through the flow restrictor concurrently with the metering step to create a zone of turbulence at the outlet end of the flow restrictor, thereby atomizing the liquid composition; heating the gas stream prior to injecting the gas stream through the flow restrictor; and adding a solid particle to the zone of turbulence concurrently with the metering and injecting steps to mix the solid particle with the atomized liquid composition, wherein the mixing at the zone of turbulence coats the solid particle with the coating material.

Schurr states that the process is for coating solid particles, in particular, small particles such as powdery or granular materials (p. 2 lines 13-15). Schurr would have been able to clearly envisage the coating of PUFA-containing or liquid pharmaceutical-containing

Art Unit: 1794

carrier particles, as well as PUFA or liquid-pharmaceutical matrix particles for use in his invention as claimed in Applicants' claims 1 and 2.

11. Schurr also speaks to repeated passes through the process to adhere additional coating materials until the desired thickness is achieved (p. 9 lines 10-15). This teaching anticipates Applicants' claim 7.

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. Claims 1-7 and 10-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schurr (WO 97/07879) in view of Mehta (4,800,087).

14. Schurr teaches a process for coating small particles with a liquid coating material as detailed above. Schurr teaches examples of coating dodecanedioic acid, a chemical intermediate, calcium carbonate, a mineral that is commonly used as a dietary supplement, and herbicides (Examples 1-4).

15. Schurr is silent as to specifically coating PUFAs or pharmaceuticals.

16. Mehta teaches a microencapsulated pharmaceutical particle (col. 3 lines 12-16). Mehta teaches that the invention may be used with "virtually any active agent" (col. 7 lines 33-35), with specific examples including analgesics, anti-inflammatory agents and

Art Unit: 1794

antibiotics taught in claims 11 and 12. The coatings taught for the encapsulation of the pharmaceutical particle include Eudragit TM, methacrylic acid ester copolymers and triacetin (col. 5 lines 40, 60-62). Mehta also teaches that his product may be used in combination with food and drink (col. 6 lines 38-40).

17. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have utilized the method as taught by Schurr in order to coat pharmaceuticals or other active ingredients such as poly unsaturated fatty acids as taught by Mehta. Both Schurr and Mehta are from the same field of endeavor in encapsulating microparticles of active ingredients. One of ordinary skill in the art would have been able to employ active ingredients as taught by Mehta in the process of Schurr without undue experimentation, and with a reasonable expectation that the resultant product would maintain the functionality of its active ingredient while at the same time be encapsulated to better withstand conditions prior to the desired release of the active ingredient. One of ordinary skill would also consider the product produced comprising the "active ingredients" of Mehta as a nutritional supplement.

18. Regarding claim 6, neither Mehta nor Schurr specifically discloses these fatty acids for use in their invention. However, the PUFAs listed are widely known as omega-3-fatty acids for use as dietary supplements. One of ordinary skill would have considered these PUFAs to be active ingredients for inclusion in an invention as taught by Schurr in view of Mehta. This would not have required undue experimentation on the part of the artisan, and would have been expected to result in a product that effectively delivered the PUFAs to the intended consumer.

Art Unit: 1794

19. Regarding claims 10-13 and the inclusion of the coated particles in food, beverages, nutritional supplements and infant formula, Mehta teaches that his product may be used in foods or beverages as detailed above. One of ordinary skill in the art at the time the invention was made would have recognize that the product produced by the method of Schurr in view of Mehta would be suitable for inclusion in virtually any type of product ingestible by a human, including food, drink or infant formula. The addition to these types of products would not have required undue experimentation on the part of the artisan, and would have been expected to result in products able to effectively deliver the active ingredient while at the same time maintaining their favorable organoleptic properties.

20. Regarding claims 14 and 15 to an animal or pet food comprising the product produced by the method, the teachings of Schurr for the production of the calcium carbonate do not state the end use of the product. However, calcium carbonate is known as a dietary supplement for both humans and animals. Therefore, one of ordinary skill in the art at the time the invention was made would have found it obvious to supplement an animal or pet food product with a pharmaceutical or PUFA particle produced by the method of Schurr in view of Mehta in order to improve the nutritional profile of the product or to deliver the active ingredient to the animal. Such an addition would not have required undue experimentation on the part of the artisan and would not have been expected to deleteriously affect the final product.

Double Patenting

21. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

22. Claims 1-3, 5, 7 and 10-12 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-5 and 9-10 of copending Application No. 10/520,539. Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications teach the encapsulation of edible particles by the same process using the same encapsulation materials and both allow for repeating the encapsulation process with the same or different coating materials..

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Art Unit: 1794

23. Claims 1-17 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-20 of copending Application No. 10/521,002. Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications teach the encapsulation of edible particles by the same process using the same encapsulation materials and both allow for repeating the encapsulation process with the same or different coating materials. Additionally, 10/521,002 teaches the loading of the carrier particles that are claimed for use in the process of both 10/523,225 (claim 1) and 10/521,002 (claim 9).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

24. Claims 1, 3, and 5-17 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-21 of copending Application No. 10/524,673. Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications teach the same process for coating or encapsulation of food particles using the same materials. Additionally, both applications teach that the coating/encapsulating process may be repeated with the same or different coating materials.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nikki H. Dees whose telephone number is (571) 270-3435. The examiner can normally be reached on Monday-Friday 7:30-5:00 EST (first Friday off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carol Chaney can be reached on (571) 272-1284. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Nikki H. Dees
Examiner
Art Unit 1794

/Carol Chaney/
Supervisory Patent Examiner, Art Unit 1794